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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,986	11/19/1999	DANIEL JOSEPH OMAHONY	99.1064.US	8043

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/443,986	OMAHONY, DANIEL JOSEPH	
	Examiner	Art Unit	
	HOPE A. ROBINSON	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *114,118-121,123-135,141 and 144* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *114,118-120 and 132-134* is/are allowed.

6)☒ Claim(s) *121, 123-131, 135, 141 and 144* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed November 2, 2007 on February 29, 2008 is acknowledged.

Claim Disposition

2. Claims 114, 118-121, 123-135, 141 and 144 are pending and are under examination.

Maintained and Amended-Claim Rejections - 35 USC э 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 121, 123-131, 135, 141 and 144 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabled for the full scope of the claims. The instant specification is enabled for the d-form retro-inverted peptide (ie, SEQ ID NO:1 or 2 etc), however is not enabled for the treatment of a mammalian disease or disorder

listed in the claims with the laundry list of drugs which broadly recites "a peptide, a hormone, a gene, a ribozyme etc. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary, Amount of direction or guidance presented, Presence or absence of working examples, Nature of the Invention, Predictability or unpredictability of the art and Breadth of the claims. The relevant factors are discussed below.

Claims 121 and the dependent claims hereto are directed to a composition comprising a d-form retro inverted peptide bound to a material comprising an active agent, wherein said active agent treats a mammalian disease or disorder, wherein said mammalian disease or disorder is selected from the group consisting of hypertension, diabetes, osteoporosis, hemophilia, anemia, cancer, migraine and angina pectoris, wherein the active agent is a drug selected from the group consisting of a peptide, a protein, a hormone…" (see the list in for example claim 121). There is no real one to one correspondence between the listing of disease/disorder and the laundry listing of drugs. For example what peptide or what hormone is within the scope of the claimed invention? The claimed invention encompasses any hormone, any protein, any gene etc. The specification does not provide adequate guidance to be able to practice the claimed invention commensurate in scope with the claims. To examine every drug to

determine if said composition will produce the effect desired would require undue experimentation.

The working example provided discusses an animal study involving the bioavailability of insulin (see for example page 26, Table 5 of the specification), however, this example does not provide support for all the mammalian diseases/disorders recited in the claims or the unspecified amount of active agents (drugs) encompassed by the claims. Therefore, it is difficult to ascertain the nature of the claimed invention from this one record.

The nature of the invention is a retro-inverted peptide that specifically binds to gastro-intestinal tract receptor. However, the specification does not provide sufficient guidance/direction to enable the full scope of the claimed invention with respect to the recitation of for example "a peptide", "a ribozyme", "an analgesic" which reads on anyone of these groupings known in the art.

It is disclosed in the specification on page 3 that the applicants have found retro-inverted forms of the GIT targeting agents specific receptor sites *in vivo* and/or promote uptake of active agents and/or enhance active agent delivery across the GIT into the systemic circulation. However, the claims are directed to any possible "active agents". The specification does not provide support for the claimed invention in association with any or all the possible proteins in nature, for example, thus the claims are overly broad.

Since very little is known in the prior art about the nature of the invention, renders the art unpredictable. The claimed invention is unpredictable since it is highly unlikely that any or all possible protein functioning in the capacity of a drug would work in the

claimed composition in the manner intended, which renders the claimed invention as unpredictable. Thus, the specification should then give more details as to how to make and use the invention in order to be enabling.

The breadth of the claims are very broad and encompass any active agent/drug in association with the claimed invention. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "…scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art…". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)*. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 121, 123-131, 135, 141 and 144 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 121 is indefinite for the recitation of " a closed set of disease/disorder with a very broad set of "active agents/drugs, which are intended for treatment of said diseases/disorder. For example, what gene is intended to treat for example migraine? Or which disease/disorder specifically aligns with what drug (no nexus between several drugs and the diseases). The dependent claims hereto are also included as well as claim 135 (which has similar language).

Response to Arguments

5. Applicant's remarks have been considered but are not persuasive. Note that the rejections under 35 U.S.C. 112, second paragraph and 112 first paragraph, remains. Applicant states that the measure of enablement is whether there is undue experimentation and that complex experimentation does not render it undue. Applicant further state that the agents are well known and that the examiner has stated what is enabled. Applicant's conclude that some experimentation is required but it is not undue and that sufficient guidance is provided. This argument is not persuasive. Undue experimentation would be required since there is no one to one correspondence between the agents/drugs and specific diseases/disorders. A skilled artisan would

have to perform undue experimentation to consider each drug/agent and determine which would affect positively the diseases/disorders. To examine every drug to determine if said composition will produce the effect desired would require undue experimentation. With respect to the 112, 2nd paragraph, applicant state that the breath of the claim has nothing to do with indefiniteness. Applicant's are correct and the issue raised is not one of breath. The issue at hand is that because the claim language is broad, a defined set is needed, for example, as asked in the rejection, what drug aligns specifically with what disease. It is unclear which drug is intended to treat what disease. Thus, as the claim has not been amended the rejection remains.

Conclusion

6. Claims 114, 118-120 and 132-134 are allowable.

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652